

REMARKS

Claims 1-73 are pending, and claims 1-4, 6-14, 22-24, 26-39, and 48-73 are currently under consideration. Applicants cancel, without prejudice, previously withdrawn claim 5 and 25. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1. Applicants note that, as indicated on the Advisory Action, Applicants' amendments filed October 15, 2004 have been entered. Accordingly, Applicants' current amendments to the claims are made with respect to the response filed and entered on October 15, 2004.
2. Applicants note with appreciation that the Examiner indicated that claims 1-4, 6-14, 48-50, 56-63, 65, and 67-69 are in condition for allowance.
3. The Examiner maintained the rejection of claims 22-24, 26-33, and 35 under 35 U.S.C. 112, first paragraph, for allegedly failing to enable one of skill in the art to practice the claimed invention. Applicants traverse the rejection and contend that the rejection is moot in light of the amended claims.

The Examiner contends that the claimed methods for treating restenosis encompass a variety of routes of administration, and that it would constitute undue experimentation for one of skill in the art to practice the claimed invention throughout this scope. Applicants respectfully continue to disagree with the Examiner's position on this point. As previously pointed out, the claimed methods are dependent upon the currently claimed elastin-based compositions. These currently claimed elastin-based compositions are attached to or otherwise formulated in association with a stent or other biocompatible device. Thus, contrary to the Examiner's assertion, the claimed methods of treating restenosis do not encompass a limitless number of possible routes of administration. Rather, the claimed methods are specific to those involving the delivery of the elastin-based composition via a biocompatible device. Such methods are amply supported by the specification, as well as by the previously submitted declaration of Dean Li. Accordingly, Applicants maintain that the claims are enabled throughout their scope.

Nevertheless, to expedite prosecution, Applicants have amended the claims to more particularly point out the claimed route of administration of the elastin-based composition.

Applicants' amendment is believed to obviate the rejection and to place these claims in condition for allowance. Specifically, in light of the specification and in light of the previously submitted declaration of Dean Li, Applicants contend that the claims are enabled throughout their scope. Applicants' amendment is made solely to expedite prosecution and is not in acquiescence to the rejection. Applicants reserve the right to prosecute claims of similar or differing scope.

Applicants respectfully point out that, in accordance with MPEP 2164.05, when making a determination as to the enablement provided for the claimed invention, the evidence must be considered as a whole. Furthermore, "the evidence provided by the applicant need not be conclusive but merely convincing to one skilled in the art." (MPEP 2164.05). In light of the specification, Applicants' amendments, the post-filing *in vivo* evidence supplied by the declaration of Dean Li, and the arguments of record, Applicants contend that this burden has been satisfied. Reconsideration and withdrawal of this rejection are respectfully requested.

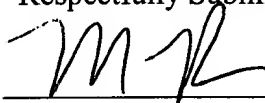
CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945, under Order No. HYDR-P01-002.**

Date: February 7, 2005

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Respectfully Submitted,



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